UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,594	10/06/2000	Yasmin Wadia	4430-57	3773

20575 7590 12/24/2002

MARGER JOHNSON & MCCOLLOM PC
1030 SW MORRISON STREET
PORTLAND, OR 97205

EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1639	12

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

file copy

Office Action Summary

Application No.	Applicant(s)
09/686,594	Wadia et al.
Examiner	**Art Unit**
Bennett Celsa	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *14-28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14-28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6 & 8*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

NOTE: the location of the present application is **ART UNIT 1639.**

Status of the Claims

Claims 14-28 are currently pending.

Election/Restriction

1. Applicant's election of Group IV (claims 14-20; and new claims 21-28) with traverse in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The abstract of the disclosure is objected to because the abstract should be in narrative form and *generally limited to a single paragraph* on a separate sheet within the range of 50 to 150 words Applicant is reminded of the proper language and format for an abstract of the disclosure.

Claim Objections

3. Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 27 is dependent on claim 27, which is not a "previous claim".

Claim Rejections - 35 USC § 112

4.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantial hemostasis" in claim 15 is a relative term which renders the claim indefinite. The term "substantial hemostasis" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 14-15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al. US Pat. No. 5,749,895 (5/98), Tayot et al. US Pat. No. 5,201, 745 (4/93) and Oz et al, WO 91/04073 (4/4/91).

Sawyer et al. teach weldable material (e.g. in the form of thin patches, sheets or films or "lamina" of varying thicknesses; e.g. see col. 3, especially lines 40-50) selected from the group consisting of biodegradable "denatured" collagen, gelatin, albumin, fibrin and elastin; which is applied to "biological tissue" and then applying energy (e.g. in the form of a laser: see col. 7-9) to weld the patch/film to the tissue in need of restructuring. See e.g. abstract and patent claims. Although, collagen is preferred, the selection of albumin from among the remaining short list of weldable materials (e.g. gelatin, albumin, fibrin and elastin) would be immediately envisaged (e.g. anticipated) or in the alternative prima facie obvious to one of ordinary skill in the art at the time of applicant's invention See e.g.. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08. The Sawyer preferred teaching of the use of " biocompatible" patches "which will not cause inflammation, toxicity or adverse immune response" (e.g. see col. 5, especially lines 35-45) would suggest to one of the ordinary skill in the art to select a human source of the material if the tissue to be treated is human; thus rendering obvious the selection of "Human serum" as the source of albumin. Additionally, Sawyer teaches not only the general applicability of tissue welding toward repairing lesions to "biological tissue", but specifically the

treatment of lung tissue (e.g. see examples and patent claims) which would be within the scope of the presently claimed "solid visceral organ". Further, Sawyer teaches the applicability of utilizing patches (e.g. collagen) to repair viscera (e.g. see col. 1; and discussion including Tayot et al. US Pat. No. 5,201,745 entitled "Visceral Surgery Patch"); which would include intestine, pancreas and hepato-biliary (e.g. liver) organs; all of which are within the scope of "solid visceral organs" as presently claimed. E.g. See Tayot at col. 1, particularly lines 55-70.

Although, Sawyer teaches laser welding, Sawyer differs from the present invention by failing to teach applying "an energy absorbing material" such as a dye (e.g. a chromophore, i.e. indocyanin green) and a "proteinaceous"soldering agent (e.g. fibrin and/or albumin) to a tissue before welding.

However, the Oz et al. reference teaches the advantages of applying "an energy absorbing material" such as a dye (e.g. a chromophore, such as indocyanin green or fluorescein isothiocyanate a.k.a. FITC) and a "proteinaceous"soldering agent (e.g. fibrin and/or albumin) (e.g. see pages 3-4; examples and claims) to a tissue before tissue welding e.g. to " lower laser energy output, which reduces the amount of collateral thermal injury, while still achieving a strong if not stronger weld than obtained using suturing techniques". See Oz pages 1-2, especially bottom of page 2".

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize "an energy absorbing material" such as a dye (e.g. a chromophore, such as indocyanin green) and a "proteinaceous"soldering agent (e.g. fibrin and/or albumin) to a

tissue before welding using the Sawyer welding method (e.g. utilizing an albumin patch) in order to realize the benefits therefrom as taught by the Oz reference (e.g. lower laser energy output etc.).

Additionally, the Oz et al. reference technique's utilization of an energy absorbing material (eg. protein solder) and a dye for use in laser welding tissue results in a laser soldering method which is quicker and safer (e.g. than suture repair) and can be applicable to trauma repair of different organs, including the "liver", renal (e.g. "kidney") and "spleen"; all of which are "hard visceral organs" within the scope of the presently claimed invention. E.g. see Oz at page 27, especially lines 10-20. In this respect , the Oz reference teaches the use of their procedure to effect "management of oozing surfaces" (e.g. achieve substantial hemostasis: e.g. present claim 15) and with respect to surgery, to clamp vessels as needed to prevent bleeding (e.g. see Oz at page 10, lines 7-15; and present claim 17) rendering these claimed embodiments prima facie obvious to one of ordinary skill in the art..

Accordingly, the Sawyer teaching of the general applicability of his tissue welding method toward repairing lesions to "biological tissue" and lung tissue; and the Sawyer teaching of the applicability of utilizing patches (e.g. collagen) to repair viscera as taught by Tayot; taken further in view of the teaching of the Oz reference to further employ an "energy absorbing material" including a dye and protein which facilitates the treatment of lesions (or trauma) to a solid visceral organ (e.g. a liver) would provide even stronger motivation to one of ordinary skill in the art to apply the Sawyer method, as modified by the Oz reference teaching , to the treatment of solid

visceral organs (e.g. the liver) using laser welding. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use the Sawyer laser welding method (as modified by the Oz reference to employ an energy absorbing proteinaceous material and a chromophore) for repairing "solid visceral organs" (e.g. liver, kidney and spleen) .

8. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al. US Pat. No. 5,749,895 (5/98), Tayot et al. US Pat. No. 5,201, 745 (4/93) and Oz et al, WO 91/04073 (4/4/91) as applied to claims 14-15, 17 and 19 above, and further in view of Gregory US Pat. No. 6,372,228 (3/02: filed 12/97 or earlier).

The combined teaching of the Sawyer, Tayot and Oz references are discussed above and herein incorporated by reference in its entirety.

The combined Sawyer, Tayot and Oz reference teachings differ from the presently claimed invention by failing to teach the incorporation of a chromophore (e.g. claim 26), such as indocyanine (e.g. claim 27) or a "biologically active agent" (e.g. claim 28) in the albumin sheet (or lamina or patch).

The Gregory patent reference (which specifically incorporates the Oz tissue welding techniques e.g. by citing WO 91/04073 in col. 6) teaches the incorporation of a dye (e.g. indocyanine) with the soldering agent or alternatively as part of the biocompatible patch material with the further optional addition of drugs, coagulants, antibiotics (e.g. "biologically active agents") to the patch (e.g. "decreasing the need for systemic intravenous or oral medications" see

col. 8, especially lines 34-52) especially when used for the repairing of "solid organs" (e.g. liver). See Gregory at col. 6-8 and patent claims (especially claims 1, 7-9, 14-16, 19-20, 33.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate a chromophore and/or a "biologically active agent" as part of a biocompatible patch material (e.g. albumin, elastin) in order to effect energy absorption (e.g. in the case of the chromophore) by alternate placement in the solder and/or patch; or with respect to the "biologically active agents" to avoid the need for external (e.g. oral/IV etc.) drug medication.

9. Claims 16, 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al. US Pat. No. 5,749,895 (5/98), Tayot et al. US Pat. No. 5,201, 745 (4/93) and Oz et al, WO 91/04073 (4/4/91) as applied to claims 14-15, 17 and 19 above, and further in view of Bass et al. US Pat. No. 5,292,362 (3/94), Gregory US Pat. No. 6,372,228 (3/02: filed 12/97 or earlier) and the specification (e.g. pages 3-4 as teaching the state of the prior art ; and specification Figures and original claims in order to demonstrate inherency). See *Ex parte Novitski*, 26 USPQ2d 1389 (B.P.A.I, 1993); MPEP 2131.01(d)

The combined teaching of the Sawyer, Tayot and Oz references are discussed above and herein incorporated by reference in its entirety.

The combined Sawyer, Tayot and Oz reference teachings differ from the presently claimed invention by failing to explicitly teach that:

1. The protein energy absorbing material (e.g. protein solder) is "fluidic" and "applied to a thickness of 100-1000 microns" (claim 18); AND

2. An albumin patch having a(n):

a. albumin concentration of "about 50% to 58% (claim 16);

b. thickness in a range of 75-300 microns (or about "250 micron" e.g. claim 23) which is "pliable" (claim 22) and "translucent" (claim 20);

c. at least about 625 Kpa tensile strength (claim 24) and

d. elasticity of about 1700 kPA to 4000kPa (claim 25).

With respect to the "viscous" nature of the solder material, the Bass patent reference teaches that protein solders (e.g. albumin containing) are generally viscous, with a protein solder solution preferred, whose viscosity can be varied for purposes of optimization (e.g. "so that delivery position and stability during welding and final elasticity and strengths are appropriate ..."). E.g. see Abstract; col. 4; patent claims.

Further, the specification (at pages 2-3) teaches that "the highest viscosity of albumin readily producible corresponds to a 55-57% aqueous solution, enabling higher tensile strength joints" ; with higher albumin concentrations being nonpreferred (e.g. dehydrate rapidly and cannot be freely handled by air").

Additionally, the Gregory patent teaches that it is preferred to make patches (e.g. sheets or lamina) as thin as possible "to allow for penetration of laser energy" (e.g. "translucent to light energy") while maintaining sufficient strength; with patch thickness being optimized in accordance

with the organ to be patched; with a disclosure by the Gregory patent of a range of thicknesses within the scope of the presently claimed invention (e.g. 100 microns - 1000 microns). See Gregory patent col. 5.

Accordingly, the Bass reference teaching of the preferred selection of "liquid" protein solder materials and additionally the "viscous nature" of the protein solder materials taught by the Bass, Gregory and Oz reference would render inherent the presently claimed limitation directed to "fluidic proteinaceous materials" (E.g. present claim 18: "fluidic").

Additionally, the prior art (e.g. Gregory and Bass) teaching and the specification admission as to the state of the prior art, permit the selection of albumin concentrations and thicknesses of albumin solder and/or lamina material (with inherent light energy translucencies and pliability) within the scope of the presently claimed invention as being obvious to one of ordinary skill in the art wishing to optimize such parameters.

Further, the selection of optimum solder viscosity and thickness; and albumin lamina thicknesses within the scope of the presently claimed invention, would necessarily and inherently result in tensile strengths and elasticities of albumin lamina as presently claimed in claims 24-25. See also specification examples and original claims demonstrating inherency of such parameters given a particular concentration and thickness of an "energy absorbing proteinaceous material" and a "biocompatible denature albumin lamina".

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)
December 20, 2002

BENNETT CELSA
PRIMARY EXAMINER